

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

### New Animal Drugs for Use in Animal Feeds; Melengestrol, Lasalocid, and Tylosin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc. The ANADA provides for use of single-ingredient Type A medicated articles containing melengestrol, lasalocid, and tylosin to make three-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Daniel A. Benz, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: [daniel.benz@fda.hhs.gov](mailto:daniel.benz@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200-430 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix, BOVATEC (lasalocid), and TYLAN (tylosin phosphate) single-ingredient Type A medicated articles to make dry and liquid, three-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter. Ivy Laboratories' ANADA 200-430 is approved as a generic copy of NADA 138-992, sponsored by Pharmacia

and Upjohn Co., a Division of Pfizer, Inc., for combination use of MGA 500 (melengestrol acetate) Liquid Premix, BOVATEC, and TYLAN in cattle feed. The application is approved as of June 1, 2006, and the regulations are amended in 21 CFR 558.342 to reflect the approval. The basis of approval is discussed in freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

### **List of Subject in 21 CFR Part 558**

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

- 2. In § 558.342, amend the table in paragraph (e)(1)(iv) in the “Sponsor” column by adding in numerical sequence “021641”.

Dated: June 23, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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